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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,550	02/27/2002	Kazuhito Rokutan	ASAM.0051	5577
38327	7590	02/03/2006	EXAMINER	
REED SMITH LLP 3110 FAIRVIEW PARK DRIVE, SUITE 1400 FALLS CHURCH, VA 22042			DEJONG, ERIC S	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 02/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/083,550	<b>Applicant(s)</b> ROKUTAN ET AL.	
	<b>Examiner</b> Eric S. DeJong	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-11 is/are pending in the application.  
 4a) Of the above claim(s) 2-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED OFFICE ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al. in light of Smith et al.

The instant claim is drawn to an oligonucleotide array comprising an array of multiple oligonucleotides with different base sequences fixed onto known and separate positions on a support substrate. Said oligonucleotides are biological stress related genes or complementary sequences of said genes and multiple oligonucleotides are classified according to their gene functions wherein the support substrate has fixation regions divided according to said classification.

[Claim 11]: Lipshutz et al. sets forth the synthesis and construction of whole genome oligonucleotide arrays with extremely high information content containing oligonucleotide sequences derived from or complimentary to genes from the human genome. See Lipshutz et al., abstract. Figure 2 of Lipshutz et al. provides a display of an oligonucleotide array from gene expression monitoring containing approximately 40,000 human genes and ESTs representative of the human genome. See also Lipshutz et al., page 21, column 1, line13 through page 22, column 2, line 29. Each set

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probe (containing only 4 probes per gene or EST) occupies a distinct and separate 22x22  $\mu\text{M}$  region in the 1.28x1.28 cm array. The separated arrangement of probes on the array allows for specific monitoring of selectable genes and serves as a sensitive, unique, and sequence specific detector. See especially Lipshutz et al., page 21, column 1, line 13 through column 2, line 16. The segregation of oligonucleotide probe sets correlating to a single gene or EST region within the human genome anticipates the claimed limitation fixing oligonucleotides onto known and separate positions on a support substrate and further classifying each oligonucleotide according to the corresponding gene function, wherein genes are classified in accordance to (1) internal and external standards genes for proof reading (construed to on housekeeping genes, see the instant specification page 7, line 21 through page 8, line 18), (2) stress-related genes related to heat shock protein and hormone genes that decreases under stress, (3) cytokine genes, (4) genes that induce cell death, (5) genes related to anti-inflammation and wound healing and genes related to cell growth inhibition, (6) transcription factor and signaling molecules related to immune response, (7) induction of cytokine, (8) transcription factor and signaling molecules related growth inhibition, and (9) transcription factor and signaling molecules. Smith et al., relied upon as a supporting document, discloses known genes within the human genome that are related (classified) to the above described functions. See for example, Smith et al., Tables 5 and 10, Examples 5, 12, and 17 and column 33, line 31 through column 34, line 60. Therefore, the oligonucleotide array disclosed by Lipshutz et al. containing approximately 40,000 identifiable, separate, and distinct probes sets representative of

the human genome inherently contains the instantly claimed classified, multiple oligonucleotides that are fixed onto known and separate positions on a support substrate.

### ***Response to Arguments***

Applicant's arguments filed 11/20/2005 have been fully considered but they are not persuasive.

In regards to the rejection of claim 11 under 35 USC § 102(b) as being anticipated by Lipshutz et al. in light of Smith et al., applicants argue that Lipshutz reference fails to teach that the support substrate has fixation regions divided according to a classification based on gene functions 1 through 9 as specified by the instant claim.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Regarding a claim to an apparatus being structurally distinguishable from the prior art, the MPEP §2114 states:

"While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a

device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).”

In the instant case, the limitation of classifying multiple oligonucleotides according to their gene function is not drawn to a structural feature of the claimed array, but rather is drawn to a functional feature. The oligonucleotide array of Lipshutz et al. provides for fixing oligonucleotides to distinct and specific positions on an array substrate. As such each oligonucleotide occupies a region on the array. Smith et al. is further relied upon to demonstrate that the whole genome arrays taught by Lipshutz et al. inherently includes sequences related to the specific genes as recited in the instant claim. A consideration of whether or not that a specific region occupied by a particular oligonucleotide occupies is further classified in accordance to a gene particular gene function does not serve to further limit the claimed array in a manner that materially effects the structure of the claimed apparatus. Therefore applicants argument is not found persuasive.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

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contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

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*John S. Brusca* 31 January 2006  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER